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10/686,129	10/14/2003	Guy W. Miller	13682.2/USC1	7630
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EXAMINER				
POLANSKY, GREGG				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,129

Applicant(s)

MILLER, GUY W.

Examiner

GREGG POLANSKY

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24-30, 34-36, 38-45 and 50-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 24-29 and 38-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30, 34-36 and 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Applicant's response, filed 6/14/2008, to the Office Action mailed 12/13/2007 is acknowledged. Applicant canceled Claims 23, 31-33, 37, and 46-49, amended Claim 30 (and withdrawn Claim 1), added Claims 50-55, and presented arguments in response to the Office Action.

2. Claims 1-22, 24-30, 34-36, 38-45 and 50-55 are pending.

3. Claims 30, 34-36, and 50-55 are presently under consideration.

4. Applicant's arguments have been fully considered and are persuasive in part.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60,284,389, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 60,284,389 fails to provide support for instant Claims 30 and 50-53, and dependent Claims 34-36, 54 and 55. '389 provides no support for fructo-oligosaccharides with specific degrees of polymerization.

Specification

6. In the previous Office Action the Specification was objected to for the following reason: The use of the trademark AUREOMYCIN, AUREOMIX, BMD, CHLOMAX, DENAGARD, LINCOMIX, MECADOX, NEO-TERRAMYCIN, PULMOTIL, TYLAN and others have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

No action has been taken by Applicant to make corrections. This objection is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 52 require a fructo-oligosaccharide having an average degree of polymerization in the range of **3-20** and **3-30** respectively. Claim 53 requires a fructo-oligosaccharide having a percent distribution of degrees of polymerization as listed in the claim; the distribution of ranges is clearly outside the range specified in Claim 30. The fructo-oligosaccharide degrees of polymerization required by Claims 51-53 fall outside the range recited in Claim 30. There is insufficient antecedent basis for these limitations in Claim 30 since Claim 30 requires a fructo-oligosaccharide "having an average degree of polymerization in the range of **2-10**" (emphasis added).

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The Specification teaches a component of the composition of Claim 30 can be **propylene** glycol (emphasis added). See page 9, lines 29-30. New Claim 55 recites that the component of Claim 30 is **polyethylene** glycol (emphasis added). This is considered to be new matter.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. In the previous Office Action Claims 30, 35, and 36 were rejected under 35 U.S.C. 102(b) as being anticipated by Teiji (Japanese Patent Publication No. 03-076561, Abstract Only). The rejection is maintained and extended to Claims 50-52 and 54.

Teiji teaches a digestion-resistant, enterobacterium (e.g., *Bifidobacterium*) containing capsule, coated with fructooligosaccharide, used to administer the bacterium to the colon without inactivating said bacterium by gastric fluids. See Abstract.

Applicant argues Teiji fails to teach the claimed invention because the claimed invention is not digested in the small intestine. Applicant quotes a section of the abstract of Teiji, "A capsule is formed of the solution of a coating film-formable and edible polymeric compound, and a plurality of holes permitting the passage of bacteria are simultaneously or subsequently formed in the capsule. Or, the capsule is formed in a state capable of being perforated in a small intestine" (emphasis added by Examiner), with the implication that this does not teach the claimed invention. This is not persuasive.

Teiji teaches all of the elements of the instant claims, i.e., a digestion resistant, fructo-oligosaccharide coated composition that is not digested or absorbed in the stomach or small intestines and that delivers enterobacteria such as *Bifidobacteria* to the colon. The "plurality of holes" in the capsule do not interfere with the stated purpose of the invention taught by Teiji, which is to feed useful enterobacteria into the colon (large intestine) without inactivating the enterobacteria with gastric juice, by way of coating the composition with digestion resistant fructo-oligosaccharide. The disclosure by Teiji of the capsule being perforated in "a small intestine" is optional (It is suspected that small intestine is a mistranslation and should have been large intestine).

As to the requirements of instant Claims 30, 50, 51, and 52 for an average degree of polymerization of 2-10, 6, 3-20, and 3-30, respectively, the fructo-oligosaccharide taught by Teiji would naturally possess this property. Applicant's definition of fructo-oligosaccharide is "partially hydrolyzed inulin with a DP in the approximate range of 2 to 20 units of β (2-1) fructose with either a glucosyl or a fuctosyl

terminus. The **average DP is less than 10 units**" (emphasis added). See page 1, lines 26-28 of instant Specification.

Therefore, the rejection is maintained and extended to Claims 50-52 and 54.

13. Claims 30, 35, and 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Leusner et al. (U.S. Patent 6,468,568 B1).

Leusner et al. teach mineral or vitamin encapsulated by fructo-oligosaccharides or inulin for controlled release. See Abstract, and column 20, "Example 1", column 21, claim 1, and column 22, claim 13. Leusner et al. teach inulin has an average degree of polymerization (DP) of "about 9 to 10", with a total range of "about 2 to more than 50", and the oligofructose (fructo-oligosaccharide) under the trade name RAFTILOSE has an average DP of "about 2-9". See column 9, lines 23-28 and lines 32-34. RAFTILOSE 95 is disclosed by Leusner as a preferred oligofructose comprising 95% oligofructose and 5% sugars. See column 9, lines 42-47. This meets the requirements of instant Claims 51 and 52 of having at least 60% or 75%, respectively, fructo-oligosaccharide, with a DP of 3-20 or 3-30, respectively.

Applicant argues the fructo-oligosaccharides taught in Leusner has "a DP of 2-4 and/or a DP of 2-8, with a mean DP of 4" (no reference to column or line numbers are provided by Applicant).

A DP of value of about 2-9 (or 2-4) falls within the ranges taught by Claims 30 and 50-52.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 30, 34-36, and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teiji (Japanese Patent Publication No. 03-076561, Abstract Only).

As previously presented (*supra*), Teiji teaches a digestion-resistant, enterobacterium (e.g., *Bifidobacterium*) containing capsule, coated with fructooligosaccharide.

Claim 53 requires a distribution of DP ranges. Page 15 of the instant Specification discloses an analysis of the fructo-oligosaccharide product bioSecure™ FOS which shows a distribution of degree of polymerization (DP) that mirrors instant Claim 53. The analysis also discloses that the product has an average DP of 6.6 and 61.8% of the product has a DP of 3-20. The Specification also discloses that the "exact composition will vary from crop to crop and from year to year"

Absent evidence to the contrary, it would be expected that the fructo-oligosaccharide of Teiji would have had a similar distribution.

Teiji does not teach a flavoring component of the coating.

Adding a flavoring agent, as needed, would have been routine to one of ordinary skill in the art at the time of the invention to produce a more palatable product.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. Claims 30, 34-36, and 50-55 are rejected.
17. No claims are allowed.
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/

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Examiner, Art Unit 1611

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614